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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,659	09/07/2006	Fiona Campbell	007193-19 US	2462

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EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
04/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,659	CAMPBELL ET AL.	
	Examiner	Art Unit	
	ALI SOROUSH	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1-12, 37-50, 52-57, 59, and 60*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,37-50,52-57,59 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Receipt

Applicant's response filed on 01/06/2009 to the Office Action mailed on 10/06/2008 is acknowledged.

Status of the Claims

Claims 1-3, 8-10, 37, 38, 43, 45, 46, 49, 50, 52-57, 59 and 60 are currently amended and claims 13-36, 51, and 58 are cancelled. Therefore, claims 1-12, 37-50, 52-57, 59, and 60 are currently pending examination for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-4, 6, 8, 12, 37, 38, 40, 41, 43, 45, and 49 under 35 U.S.C. 102(b) as being anticipated by Casswall et al. (Bovine Anti-Helicobacter pylori Antibodies for Oral Immunotherapy, Published 2002) as evidenced by Hemling (Iodine in Milk, Published 10/18/2001) and Dial et al. (Antibiotic Properties of Bovine Lactoferrin on Helicobacter pylori, Published 1998) **is maintained**.

Casswall et al. teach, "An anti-H. pylori bovine colostral hyperimmune immunoglobulin preparation (BIC) was generated and its efficacy was tested in different in vitro experiments ..." (See abstract). "Milk or colostrum from cows immunized with different antigens has previously been shown to be an effective and safe source of orally administered antibodies for both prophylaxis and therapy ... Hence, we produced a bovine immunoglobulin colostral preparation (BIC), which was used in therapeutic experiments in a H. pylori mouse model." (See page 1380, column 2, Lines 11-19 and page 1381, column 1, Lines 1-2). "The ability of the BIC to block the binding of H. pylori to gastric tissue in situ was compared with other bovine colostrum Ig preparations." (See page 1381, column 1, Lines 9-13). "The BIC preparation was then compared with a control preparation from non-immunized cows for its inhibition of binding of H. pylori to human gastric mucosa in situ. Almost 90% of blocking was observed when 0.1 mg/mL of the BIC was preincubated with H. pylori before incubation with human gastric mucosa tissue sections. BIC (1mg/mL) completely blocked the binding." (See page 1382, column 2, Lines 39-47). Caswell et al. further teach, "Much interest is currently focused on Helicobacter pylori infection and its association with development of gastritis, peptic ulcers and gastric malignancies in humans." (See page 1380, column 1, Lines 1-4). Caswell et al. conclude that "Bovine colostral antibodies against H. pylori can be generated in high titres, inhibit binding in vitro and can eradicate or reduce the number of bacteria in infected mice." (See abstract).

With regard to the composition comprising a mucolytic agent Hemling teaches that "lactating women secrete milk with 60 to 281 mu g/l iodine" (See page 1, paragraph

4) and also indicates that commercial (bovine) milk also contains an amount of iodine. (Se page 3, Table 3). Since applicant indicates iodine (See Specification page 12, Line 15) is one such mucolytic agent and therefore drinking the composition taught by Caswell et al. would necessarily result in inhibition and/ or reduction of bacterial colonization of mucous epithelium, reduction of damage to mucous epithelium associated with bacterial infection, and treat a disease or condition associated with bacterial infection of mucous epithelium.

With regard to the composition comprising lactoferrin, Dial et al. indicates that bovine colostrum contains lactoferrin which has antibiotic properties against H. pylori. (See title and page 2754, column 2, Lines 10-14). Therefore, the composition of Caswell et al. inherently has lactoferrin and antibiotic activity against H. pylori. For the foregoing reasons the instant claims are anticipated by the prior art.

Response to Applicant's Argument

Applicant argues that in view of the instant amendments none of the cited references teach each and every element of the claimed invention. Applicant's arguments have been fully considered but found not to be persuasive. Casswall et al. teach application of colustrum from cows immunized with antigens against H. pylori to human gastric mucosa, resulting in the inhibition of bacterial colonization. Dial et al. and Hemling teach that cow colustrum has both lactoferrin and iodine. Applicant's specification indicates iodine is a mucolytic agent. Therefore, each and every element of the instant claim is taught by Casswall et al. For the foregoing reasons the instant

rejection claims 1-4, 6, 8, 12, 37, 38, 40, 41, 43, 45, and 49 under 35 U.S.C. 102(b) is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. The rejection of claims 5, 7, 9, 10, 11, 39, 42, 46, 47, 48, 54, 55, 56, and 57 under 35 U.S.C. 103(a) as being unpatentable over Casswall et al. (Bovine Anti-Helicobacter pylori Antibodies for Oral Immunotherapy, Published 2002) in view of Burggraber et al. (US Patent Application 2003/0180381 A1, Published 09/25/2003) and as evidenced by Dial et al. (Antibiotic Properties of Bovine Lactoferrin on Helicobacter pylori, Published 1998) **is maintained**.

Applicant Claims

Applicant claims method of inhibiting bacterial colonization of mucous epithelium, reducing bacterial infection of mucous epithelium, reducing damage to mucous epithelium associated with bacterial infection, and method for treating a disease or condition associated with bacterial infection of mucous epithelium by administering a composition comprising a mucloytic agent and a milk product. Applicant further claims the aforementioned composition.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Casswall et al. teach, "An anti-H. pylori bovine colostral hyperimmune immunoglobulin preparation (BIC) was generated and its efficacy was tested in different in vitro experiments ..." (See abstract). "Milk or colostrum from cows immunized with different antigens has previously been shown to be an effective and safe source of orally administered antibodies for both prophylaxis and therapy ... Hence, we produced a bovine immunoglobulin colostral preparation (BIC), which was used in therapeutic experiments in a H. pylori mouse model." (See page 1380, column 2, Lines 11-19 and page 1381, column 1, Lines 1-2). "The ability of the BIC to block the binding of H. pylori to gastric tissue in situ was compared with other bovine colostrum Ig preparations." (See page 1381, column 1, Lines 9-13). "The BIC preparation was then compared with a control preparation from non-immunized cows for its inhibition of binding of H. pylori to human gastric mucosa in situ. Almost 90% of blocking was observed when 0.1 mg/mL of the BIC was preincubated with H. pylori before incubation with human gastric mucosa tissue sections. BIC (1mg/mL) completely blocked the binding." (See page 1382, column 2, Lines 39-47). Caswell et al. further teach, "Much interest is currently focused

on Helicobacter pylori infection and its association with development of gastritis, peptic ulcers and gastric malignancies in humans." (See page 1380, column 1, Lines 1-4). Caswell et al. conclude that "Bovine colostral antibodies against H. pylori can be generated in high titres, inhibit binding in vitro and can eradicate or reduce the number of bacteria in infected mice." (See abstract).

Dial et al. teach that bovine colostrum contains lactoferrin which has antibiotic properties against H. pylori. (See title and page 2754, column 2, Lines 10-14).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

The therapeutic composition taught by Casswall et al. lacks a teaching wherein the composition comprises acetylcysteine as the mucolytic agent. This deficiency is cured by the teachings of Bruggraber et al.

Bruggraber et al. teach, "Cobalt salts have been found to be particularly effective against H. pylori and may therefore be used to treat gastrointestinal infection with this bacteria ... Treatment with the cobalt salts may be carried out at the same time as conventional treatment with an antibiotic and/or proton pump inhibitor." (See abstract). "The cobalt ions may be used together with one or more agents which facilitate targeting together with one or more agents which facilitate targeting to the mucous layer. For example, the cobalt salt may be used together with agents selected from the group consisting of ... mucolytic agents (such as acetylcysteine, guaiphensin or ammonium citrate) ..." (See paragraph 0035). Bruggraber et al. further teach that one

common conventional treatment used on H. pylori infection is complex triple therapies based on lansoprazole, amoxicillin, and metronidazole. (See paragraph 0019).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the bovine colostral hyperimmune immunoglobulin preparation taught by Casswall et al. to the treatment composition taught by Bruggraber at al., as suggested by Bruggraber et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Bruggraber et al. teach that the treatment with cobalt may be carried out at the same time as conventional treatment. Casswall et al. teach that BIC has the ability to inhibit binding of H. pylori to gastric mucosa. Therefore, the combined compositions have the additive effect of treating gastrointestinal infections.

The examiner notes that Dial et al. teach that colostrum has lactoferrin. Therefore, it is implicit to the BIC that it also contains an amount of lactoferrin.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Applicant's Argument

Applicant argues that in view of the instant amendments none of the cited references teach each and every element of the claimed invention. Applicant's arguments have been fully considered but found not to be persuasive. Casswall et al. teach application of colustrum from cows immunized with antigens against H. pylori to human gastric mucosa, resulting in the inhibition of bacterial colonization. Dial et al. and Hemling teach that cow colustrum has both lactoferrin and iodine. Applicant's specification indicates iodine is a mucolytic agent. Therefore, each and every element of the instant claim is taught by Casswall et al. . For the foregoing reasons the rejection of claims 5, 7, 9, 10, 11, 39, 42, 46, 47, 48, 54, 55, 56, and 57 under 35 U.S.C. 103(a) is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616

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